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Original article

National comparison of oncologic quality indicators between open and robotic-assisted radical cystectomy

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Abstract

Introduction: Despite increased adoption of robotic-assisted radical cystectomy (RARC), no national data have validated its oncologic efficacy compared to the "standard" open radical cystectomy (ORC). Positive surgical margins (PSM) and lymph node (LN) yield during radical cystectomy (RC) have an established relationship with bladder cancer outcomes. Here, we propose these 2 as quality indicators for RC and assess their differences to compare the oncologic efficacy between RARC and ORC.

Methods: Using the National Cancer Data Base for the years 2010 to 2012, all patients who underwent ORC or RARC were analyzed. Baseline demographic and cancer stage information were compared as well as unadjusted rates of PSM and LN yield. Survival effect of each indicator was assessed. Using propensity score adjustment, rates of PSM and LN yield were compared between RARC and ORC.

Results: A total of 12,036 patients are included who underwent RC, 20% (2,397) of which were performed robotically. Percentage RARC of total RC increased from 16.2% to 23.3% over the 3 study years. Compared to ORC, patients who underwent RARC were no different in age but were more often men (78.4% vs. 73.6%, $P < 0.001$), had less-advanced cancer stage, and were more likely to have received neoadjuvant chemotherapy (20.9% vs. 14.5%, $P < 0.001$). Most RARC procedures were performed at academic medical centers (66.1%). Unadjusted rates of PSM were lower in the RARC group (10.8% vs. 13.2%, $P = 0.002$) whereas median LN yield was higher in RARC patients (16 [interquartile range 9, 25] vs. 11 [interquartile range 5, 19], $P < 0.001$). After propensity score covariate adjustment, there was no significant difference in PSM rate between RARC and ORC (-1.12% difference, [95% CI: -2.8, 0.32%]. However, RARC was associated with a higher node yield ($+3.32$ LN, [95% CI: 2.61, 4.03]) than ORC ($P < 0.001$).

Conclusion: The RARC is becoming more prevalent. In a national cohort, RARC was performed more often on men, with lower stage cancer, who were more likely to receive neoadjuvant chemotherapy. Controlling for these factors, RARC had comparable PSM rates but slightly higher LN yield than ORC. © 2016 Elsevier Inc. All rights reserved.

Keywords: Bladder cancer; Open radical cystectomy; Robotic-assisted radical cystectomy; Outcomes; Surgical margins; Lymph node yield

1. Introduction

Radical cystectomy (RC) with urinary diversion is the standard of care for nonmetastatic, muscle-invasive bladder cancer [1,2]. Open radical cystectomy (ORC), the standard approach, has 30-day complication rates as high as 58% [3]. In an effort to reduce the morbidity of this procedure, robotic-assisted radical cystectomy (RARC) has been adopted as a minimally invasive alternative. Early series in 2003 [4] described excellent results in expert hands, and

the incidence of RARC has increased from 0.6% in 2004 to 12.8% in 2010. This widespread adoption of RARC has increased despite the lack of comparative efficacy data showing a benefit over traditional ORC [5].

Similar to debates in prostate cancer, the true benefit of the surgical approach is controversial. The cost of the technology and the learning curve of the procedure must be considered along with any potential differences in oncologic efficacy and morbidity benefit. This has been well studied at high-volume academic hospitals with a prospective observational study finding RARC to have a significant reduction in early postoperative morbidity with fewer major complications despite the RARC cohort having higher Charlson

comorbidity scores [6]. Another retrospective study found RARC to have shorter length of stay (LOS), decreased odds of minor complications, but similar odds of major complications [5]. Finally, a recent prospective randomized controlled trial met futility criteria and closed at interim analysis because of similar rates of complications at 90-day postoperatively between ORC and RARC groups. In this study, both groups had similar positive surgical margins (PSM), lymph node (LN) yields, LOS, and quality-of-life scores, with cost favoring ORC [1].

Given the increased adoption of RARC, especially in the community setting, a broad analysis of the patient demographic undergoing RARC as well as a comparison of oncologic quality indicators is necessary. The success of the procedure at referral centers may not necessarily be translated outwardly to the community. In this study, we sought to (1) identify the patient and hospital characteristics that are associated with RARC and (2) to propose and compare 2 oncologic quality indicators: PSM rate and LN yield between the 2 approaches as a means of comparing efficacy on a national level. It was our goal to highlight trends in utilization of RARC with special attention to oncologic quality.

2. Methods

2.1. Population overview

The National Cancer Data Base (NCDB) is a joint project of the American Cancer Society and the Commission on Cancer of the American College of Surgeons. Established in 1989, the NCDB is a nationwide, facility-based, comprehensive clinical surveillance resource oncology data set that captures 70% of all newly diagnosed malignancies in the United States annually. Over 1,500 hospitals with accredited cancer programs submit standardized data regarding patient demographics, comorbidities, tumor characteristics, cancer staging, details regarding the first treatment course administered, and patient outcomes (including length of stay, unplanned 30-day readmission, and 30-day mortality). Further information on the NCDB can be found at http://ncdbpuf.facs.org/.

2.2. Patient selection

The institutional review board approval is not required for ethically preapproved de-identified national data sets at our institution. We queried years 2010 to 2012 of the NCDB to identify patients with bladder cancer undergoing radical cystectomy. Bladder cancer was identified using International Classification of Diseases for Oncology—third Edition (ICD-O-3) code C67.X. Radical cystectomies were identified with the ICD-9-CM procedure codes of 60, 61, 62, 63, and 64. Pelvic exenterations performed for bladder cancer were also included using the following ICD-9-CM

procedure codes: 70, 71, 72, 73, and 74. RARC and ORC were differentiated based on "operative approach" variable within the NCDB. Cases with approach variable of "endoscopic" or "laparoscopic" were excluded, as were those cases for which the surgical approach was unknown or when a conversion to open surgery occurred. Complete American Joint Committee on Cancer clinical TNM staging was used when available (85.1% of patients). In patients missing staging information, final pathologic staging was used as a surrogate to develop a composite variable. Age was categorized into 4 even quartiles: 27 to 61, 62 to 69, 70 to 76, and 77+ years old. The LN yield was used as a continuous variable and grouped into 3 categories (lower quartile [0–6 LN], middle 50% [7–20 LN], and upper quartile [21+ LN]) for survival analysis.

2.3. Outcomes and statistical analysis

Mean patient age was compared using Student's *t*-test, whereas Chi-squared analyses were employed for comparison of categorical data. Nonnormally distributed continuous data were compared via Mann-Whitney or Kruskal-Wallis test. Our primary outcome was the comparison of 2 quality indicators between ORC and RARC: rate of PSM and LN yield. PSM was determined by coding of either gross residual tumor or microscopic/macroscopic positive margins. To evaluate for survival significance, and thus clinical importance of each quality indicator, survival analyses were completed using the Kaplan-Meier method comparing negative and PSM as well as lower quartile (0–6 LN), middle 50% (7–20 LN), and upper quartile (21+ LN) of LN yield. Median survival time was assessed and the log-rank test for equality of survival function was calculated.

Unadjusted PSM rates and LN yield were assessed. Propensity score adjustment was then performed using the covariate adjustment method [7]. The initial regression model for propensity adjustment for the treatment variable (surgical approach: RARC or ORC) was constructed for patient age, sex, race, Charlson/Deyo score, urban/rural and geographic location, insurance status, income, composite American Joint Committee on Cancer stage, hospital type, chemotherapy status, and year to best adjust each cohort. As there were higher rates of neoadjuvant chemotherapy (NAC) given in the RARC group, sensitivity analysis was performed using both clinical and pathological T-classification compared to the composite staging variable. This was performed owing to concerns of underestimation of staging when using final pathologic information to account for missing clinical data in our composite variable. The Hosmer-Lemeshow goodness-of-fit test was completed to confirm appropriateness of this model. This propensity score was then used in a separate regression model to determine the association of operative approach (RARC vs. ORC) with each of our 2 outcomes: PSM rates and LN yield. All data analysis was performed with STATA v13 software.